

## **REMARKS**

Claims 1-6, 8, 10-20, 35-61 are pending.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the outstanding Office Action.

### **Claim Rejections Under 35 U.S.C. § 112, second paragraph**

Claims 3 and 40 are rejected under 35 U.S.C. § 112, 2nd paragraph, as allegedly being indefinite. The Examiner argues that the term "the ostium diameter" has no antecedent basis.

Applicants submit that such term is not indefinite for lacking antecedent basis, just like "the diameter" of a circle is not indefinite. See MPEP 2173.05(e):

**"A CLAIM IS NOT PER SE INDEFINITE IF THE BODY OF THE CLAIM RECITES ADDITIONAL ELEMENTS WHICH DO NOT APPEAR IN THE PREAMBLE**

The mere fact that the body of a claim recites additional elements which do not appear in the claim's preamble does not render the claim indefinite under 35 U.S.C. 112, second paragraph. See *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the Larsen claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The examiner rejected the claim under 35 U.S.C. 112, second paragraph, because the omission from the claim's preamble of a critical element (i.e., a linear member) renders that claim indefinite. The court reversed the examiner's rejection and stated that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, paragraph 2.)".

Nevertheless, Applicants have amended Claims 3, 40, and 58 to avoid any potential confusion. Applicants submit that the amendments do not narrow the scope the claims. Reconsideration and withdrawal of the indefiniteness rejection are respectfully requested.

### **Claim Rejections Under 35 U.S.C. § 103**

Claims 1-6, 8, 10-14, 17, 18, and 35-40 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Logan (of record) and further in view of White (of record).

Claims 19-20 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Logan and White in view of Scholz (or record).

Applicants have argued previously, and hereby reiterate that none of the cited art disclose the claim limitation "... the distal portion having an annular element comprising a graft retention component to secure the tissue ..." (emphasis added). Therefore, the cited art, either alone or in combination (assuming for the sake of argument that they can be combined as suggested, which Applicants do not concede) cannot render the claimed invention obvious.

The Examiner argues in the instant Office Action that "... the entire apparatus of Logan has an annular shape as seen in Logan Figures 2-4" (emphasis added). Applicants respectfully disagree.

First of all, the claim does not recite the "entire apparatus" to be annular. Rather, it is the distal portion of the apparatus that has an annular element.

Secondly, "annular" means "of, relating to, or forming a ring" according to the Merriam-Webster Online Dictionary. The same dictionary further define "ring" as "a circular band ...". This definition is consistent with the intrinsic evidence of how this term is used and means in the instant application.

As the Federal Circuit held in the seminal claim construction case *Phillips v. AWH Corp.*, "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" 415 F.3d 1303, 1315 (Fed. Cir. 2005) (*en banc*) (emphasis added, quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

Also see *Nystrom v. TREX Co.*, 424 F.3d 1136, 1145 (Fed. Cir. 2005) ("[I]n the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to the public - *i.e.*, those of ordinary skill in the art - that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the

intrinsic record, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source.”) (emphasis added).

Therefore, established case law requires the meaning of the disputed claim term to be construed based on "the context of the intrinsic record" – "the specification" of the application. Any extrinsic sources, to the extent that their interpretation of the disputed term is *different from* or *inconsistent with* the meaning based on the intrinsic record, should not be relied upon.

Here, the instant specification clearly uses the term "annular" in a way that is consistent with the plain and ordinary meaning of the term (see the authoritative dictionary definition). Such a definition, however, does not encompass the situation in Logan where the depicted structure has a "discontinuous" shape, one that is certainly not circular or "annular." The Examiner's position, in contrast, appears to be based on personal opinion that is not even supported by any extrinsic dictionary or treatise definition, or any other extrinsic source.

Furthermore, page 15, lines 22-25 of Logan states that “[t]he flexible nature of the nitinol material and the discontinuity of medial portion 208 permits connector to expand and contract with respect to diameter 212” (emphasis added). This discontinuity of medial portion 208 is essential for the function of the connector assembly in Logan, since mounting the connector assembly in Logan onto the annular recess 154 of the connector support member 152 requires the connector assembly to be expandable and/or retractable.

Therefore, Logan fails to disclose the use of any “annular element” as recited in the pending claims in its connector assembly, especially not any annular element that has a "fixed cross-sectional area" as recited in Claims 41 and 47. Applicants note that the Examiner does not dispute this argument about Claims 41 and 47. Thus at the least, Claims 41 and 47 are allowable over the cited art.

Furthermore, Applicants submit that Logan describes a device suitable for an "axial end to side" anastomosis connection, which device could not provide a connection area larger than that of the native graft circumference. Therefore, Logan does not teach the subject matter of dependent Claim 3, and the other cited art fail to remedy this deficiency. Thus at least Claim 3 is allowable over the cited art.

Reconsideration and withdrawal of the obviousness rejection are respectfully requested.

Applicants further submit that, upon allowance of the elected product / apparatus claims, Applicants respectfully request the Examiner to rejoin and examine the currently withdrawn method Claims 51-61, which depend from or otherwise require all the limitations of the patentable product.

### CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance. The Examiner is invited to telephone the undersigned to discuss any issue pertaining to this response. Applicants request favorable consideration of the application and early allowance of the pending claims.

Applicants believe no fee is due in connection with the filing of this response. However, if any fee is due, please charge our Deposit Account No. 18-1945, from which the undersigned is authorized to draw under Order No. 000293-0059-101.

Dated: February 25, 2009

Respectfully submitted,

By \_\_\_\_\_  
Yu Lu, Ph.D., J.D.

Registration No.: 50,306  
ROPES & GRAY LLP  
One International Place  
Boston, Massachusetts 02110  
(617) 951-7000  
(617) 951-7050 (Fax)  
Attorneys/Agents For Applicant